

2. Defendant Mylan, Inc. is a corporation organized and existing under the laws of the State of Pennsylvania. Mylan, Inc. has done and is doing business in Nebraska. Mylan, Inc. may be served by delivering a summons and copy of the complaint to its President, Robert J. Coury, at 781 Chestnut Ridge Road, Morgantown, WV 26505, or any other officer or managing agent at such address.
3. Defendant Mylan Pharmaceuticals, Inc., a subsidiary of Mylan, Inc., is a corporation organized and existing under the laws of the West Virginia. Mylan Pharmaceuticals, Inc. has done and is doing business in Nebraska. Mylan Pharmaceutical may be served by delivering a summons and copy of the complaint to its President, Harry A. Korman, at 781 Chestnut Ridge Road, Morgantown, WV 26505, or any other officer or managing agent at such address.
4. Defendant Mylan Technologies, Inc., a subsidiary of Mylan, Inc., is a corporation organized and existing under the laws of the State of West Virginia. Mylan Technologies, Inc. has done and is doing business in Nebraska. Mylan Technologies may be served with process by delivering a copy of the summons and the complaint to its President, Carolyn Myers, at 1500 Corporate Drive, Suite 400, Cannonsburg, PA 15317, or any other officer or managing agent at such address.

JURISDICTION AND VENUE

5. Pursuant to 28 U.S.C. § 1332, this Court has jurisdiction over this case because it is a lawsuit between parties of diverse citizenship and the amount in controversy exceeds \$75,000. Venue is proper in this Court under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim (i.e., Decedent's fentanyl overdose and

resulting death) occurred in this district.

FACTS

6. This suit arises out of the wrongful death of Decedent, due to the wrongful conduct of Defendants. Decedent was given a prescription for 50 mcg fentanyl patches. The prescription was filled with 50 mcg Mylan (fentanyl transdermal system) patches from a local pharmacy. Decedent was wearing one of these patches (the “Houston Patch”) at the time of her death and it was the cause of her death. The Patch worn by Decedent at the time of her death was designed, manufactured, marketed, and distributed by the Mylan Defendants.
7. The Patch is a matrix patch containing the drug fentanyl. Fentanyl is an extremely dangerous drug that is at least 80 times stronger than morphine. Fentanyl is classified as a Schedule II controlled substance by the FDA and is generally used to relieve pain.
8. The Patch is applied by the patient and delivers fentanyl through the patient’s skin. The Mylan Defendants design, manufacture, market and sell the Patch with the intention that it will release a certain amount of fentanyl into a patient at a certain rate, and thus produce a certain level of fentanyl in the blood of the patient. In other words, if a Patch functions as intended and it is properly used by the patient, the patient should not receive a harmful dose of fentanyl. Decedent never abused the Patch or used it inappropriately.
9. The Patch is unsafe for its intended or reasonably foreseeable use because it can and does cause lethal levels of fentanyl in patients. Prior to the time Decedent’s patch was manufactured and distributed, numerous patients received lethal doses of fentanyl while using the Patch as prescribed. The Mylan Defendants knew or should have known that

patients were receiving lethal fentanyl doses from proper use of the Patch because of wrongful death lawsuits filed against them, from the FDA's adverse event reporting system, and adverse event reports from medical examiners and the World Health Organization.

10. Decedent was prescribed Mylan 50 mcg patches for pain. Decedent died on September 10, 2007. Decedent had a fatal blood fentanyl level at the time of her death and the cause of death listed on her death certificate is drug toxicity.

CAUSES OF ACTION

FIRST CAUSE OF ACTION STRICT PRODUCT LIABILITY WRONGFUL DEATH

11. Plaintiff re-alleges and incorporates by reference the consistent allegations in the preceding paragraphs.
12. The Mylan Defendants are liable under the theory of product liability as set forth in §§402A and 402B of the Restatement of Torts 2d and/or the § 6 of the Restatement of Torts 3d. The Mylan Defendants at all times material hereto engaged in the business of designing, manufacturing, selling, marketing, and/or supplying the Patch, including the Houston Patch.
13. The Houston Patch was in a defective condition at the time it was designed, manufactured, sold, and/or marketed by the Mylan Defendants and at the time it left their possession because it was defectively manufactured, defectively designed, and contained insufficient warnings concerning its risks. These defects made the Houston Patch unreasonably dangerous (i.e., created a risk of harm beyond that which would be

contemplated by the ordinary foreseeable user) for its intended or reasonably foreseeable use. The Houston Patch was unreasonably dangerous and, therefore, defective because, *inter alia*, it gave Decedent a much higher dose of fentanyl than a properly functioning patch should have given her.

14. Decedent was unaware of the defective condition of the Houston Patch at the time she used the product in the manner and for the purpose it was intended. The defective condition was a proximate cause of Decedent's death and the damages described herein.
15. The Houston Patch was in the control of the Mylan Defendants at the time the defect occurred. Further, the injury sustained by Decedent, fentanyl intoxication, was the exact type of injury that a defective Patch causes. The Houston Patch reached Decedent without any substantial change in its condition. The Houston Patch presented an unreasonable risk of injury in that the risk was one which a reasonably prudent person having full knowledge of the risk would find unacceptable. Because of the nature of ingredients or natural characteristics of the Houston Patch, use of it involved a substantial risk of injury. The exposure to risk of injury was unreasonable taking into consideration a balancing of the dangers and benefits resulting from the product's use. Without limitation, the Houston Patch was defective because it malfunctioned and did not perform as intended and designed.

1. Manufacturing Defect

16. More specifically, the Houston Patch was defective because of the existence of a manufacturing flaw which rendered the product unreasonably dangerous at the time it left the Mylan Defendants' control. The Houston Patch was unreasonably dangerous because

it failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner. The Houston Patch was unreasonably dangerous beyond that which would be contemplated by the ordinary foreseeable user. The manufacturing defect was a legal cause of Decedent's death and the damages claimed herein. Without limitation, the Houston Patch was defective because it malfunctioned and did not perform as intended and designed.

2. Failure to Warn

17. Pleading further and without waiver of the foregoing, the Houston Patch was defective because the Mylan Defendants failed to warn of risks that were known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time the Houston Patch was manufactured and distributed. The Mylan Defendants knew or had reason to know the Patch was or was likely to be unreasonably dangerous in the use for which it was made. Decedent was unaware of these risks, which were not readily recognizable by an ordinary consumer using the product in a reasonably foreseeable manner. The Mylan Defendants failed to warn Decedent or her doctor of the dangerous condition of the Houston Patch or the facts that made it dangerous. The Mylan Defendants' failure to warn was a proximate cause of Decedent's death and the damages claimed herein.

3. Design Defect

18. Pleading further and without waiver of the foregoing, the defective design of the Houston Patch made it unreasonably dangerous because it failed to perform as safely as an ordinary consumer would expect when used an intended or reasonably foreseeable

manner. The Houston Patch failed to comply with existing technology or the state of the art.

19. The Mylan Defendants, who participated in the design of the Patch, could have provided a safer alternative design. The foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design and the omission of the alternative design renders the product not reasonably safe. The safer alternative design, in reasonable probability, would have prevented or significantly reduced the risk of Decedent's death without substantially impairing the Patch's utility and that was economically and technologically feasible at the time the product left the control of the Mylan Defendants by the application of existing or reasonably achievable scientific knowledge. The design defect was a proximate cause of Decedent's death and the damages claimed herein.

**SECOND CAUSE OF ACTION
STRICT PRODUCT LIABILITY
SURVIVAL ACTION**

20. Plaintiff re-alleges and incorporates by reference the consistent allegations in the preceding paragraphs.
21. The defective condition of the Houston Patch was proximate cause of Decedent's conscious pain and suffering prior to death and the damages claimed herein.

**THIRD CAUSE OF ACTION
NEGLIGENCE
WRONGFUL DEATH**

22. Plaintiff re-alleges and incorporates by reference the consistent allegations in the preceding paragraphs.

23. The Mylan Defendants had a duty to exercise reasonable care in the design, manufacture, marketing, sale or distribution of the Patch into the stream of commerce, including but not limited to, a duty to assure that the Patch did not cause users to suffer from dangerous side effects, including death.
24. The Mylan Defendants knew or should have known that the Patch was or was likely to be dangerous (i.e., create a high risk of dangerous side effects, including death) when put to the use for which it was made. Further, the Mylan Defendants knew or had reason to know that patients and their prescribing doctors would not realize the danger. The Mylan Defendants failed to exercise reasonable care in the design, manufacture, marketing, testing, approval, application for approval, inspection, sale, quality assurance, reporting to the FDA, quality control, and/or distribution of the Houston Patch to see that the patch was safe for the use for which it was made.
25. More specifically, the Defendants' negligence in the design, manufacture, marketing, testing and sale of the Patch, includes but is not limited to their:
 - a. Providing misleading, inadequate, and/or insufficient warnings regarding the Patch to Decedent, a foreseeable user of the Patch, or to her prescribing doctor;
 - b. Failure to use due care in designing and manufacturing the Patch;
 - c. Failure to use proper materials reasonably suited to the manufacture of the Patch;
 - d. Failure to provide to the FDA information or data relevant to the safety of the Patch;
 - e. Failure to obtain easily accessible information or data relevant to the safety of the Patch;

- f. Not performing sufficient testing of the Patch to confirm or ensure it was safe for its intended use;
- g. Failure to use due care to test and inspect the Patch to determine its durability and functionality for the purpose for which it was intended;
- h. Failure to ensure the Patch is made without defects;
- i. Failure to conduct adequate testing and post-marketing surveillance to determine the safety of the Patch;
- j. Misrepresenting that the Patch is safe for use;
- k. Inadequate or insufficient inspection for defects;
- l. Inadequate and/or insufficient research into the safety of the product prior to sale;
- m. Inadequate and/or insufficient monitoring or research regarding adverse events;
- n. Failure to list death as an adverse event;
- o. Failure to provide adequate training, knowledge or information to physicians, distributors, or sellers of the product;
- p. Marketing the Patch for unsafe uses;
- q. Failure to adequately warn individuals of the dangerous and lethal side effects of the product;
- r. Formulating and designing the product;
- s. Making the product;
- t. Inspecting and testing the product; and/or
- u. Packaging the product; and
- v. Other and further particulars as will be proven at trial.

26. The negligent conduct of the Mylan Defendants, as alleged above, was a proximate cause of Decedent's death and the damages claimed herein.

**FOURTH CAUSE OF ACTION
NEGLIGENCE
SURVIVAL ACTION**

27. Plaintiff re-alleges and incorporates by reference the consistent allegations in the preceding paragraphs.
28. The negligent conduct of the Mylan Defendants, as alleged above, was a proximate cause of Decedent's conscious pain and suffering prior to death and the damages claimed herein.

**FIFTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION
WRONGFUL DEATH**

29. Plaintiff re-alleges and incorporates by reference the consistent allegations in the preceding paragraphs.
30. The Mylan Defendants knew that the Patch created a high risk of unreasonable, dangerous side effects, including that proper use of the Patch can cause death, but Mylan failed to communicate to the FDA, Decedent, physicians, distributors, pharmacists, and/or the general public, that proper use of the Patch could cause serious injury and/or death.
31. Therefore, Plaintiff brings this cause of action against the Mylan Defendants under the theory of negligent misrepresentation for the following reasons:
- a. The Mylan Defendants failed to warn of the defective condition of the Patch, as manufactured and/or supplied by the Mylan Defendants;

- b. The Mylan Defendants, individually, and through their agents, representatives, distributors and/or employees, falsely misrepresented material facts about the Patch in the course of their business in that they made such misrepresentations when they knew of the falsity of such misrepresentations. Alternatively, the Mylan Defendants made such misrepresentations recklessly without knowledge of the truth of the representations and as positive assertions;
- c. The above misrepresentations were made to the FDA, Decedent, physicians, pharmacists, as well as the general public;
- d. The Mylan Defendants intended to induce others to rely on their representations, including, without limitation, Decedent, physicians, and pharmacists;
- e. Decedent and others, including, without limitation, Decedent's physician(s) and her pharmacist(s), justifiably relied on Defendants' misrepresentations; and
- g. Consequently, Decedent's use of the Patch was to her detriment. The Mylan Defendants' fraudulent misrepresentations were a proximate cause of Decedent's death and the damages claimed herein.

**SIXTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION
SURVIVAL ACTION**

- 32. Plaintiff re-alleges and incorporates by reference the consistent allegations in the preceding paragraphs.
- 33. The Mylan Defendants' fraudulent misrepresentations were a proximate cause of Decedent's conscious pain and suffering prior to death and the damages claimed herein

DAMAGES

34. The unlawful acts and practices described above were a proximate cause of Decedent's death, her conscious pain and suffering prior to death, and the damages claimed in this lawsuit. Therefore, Plaintiff, on behalf of Decedent's Estate and Decedent's wrongful death beneficiaries, seeks all damages available under Nebraska law including, without limitation: (a) the loss of Decedent's likely future financial contributions; (b) the loss of Decedent's services; (c) the loss of Decedent's society, comfort, and companionship; and (d) Decedent's medical, funeral expenses, and burial expenses.

CONDITIONS PRECEDENT

35. All conditions precedent to Plaintiffs' right to recover the relief sought herein have occurred or have been performed.

DEMAND FOR JURY TRIAL

36. Pursuant to Federal Rule of Civil Procedure 38, Plaintiff hereby demands trial by jury on all issues.

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that the Mylan Defendants be cited to appear and answer, and that the Court set the case for jury trial, and that judgment be entered against Defendants, jointly and severally, for the damages set forth herein above; for pre-judgment and post-judgment interest and costs of suit; and for such other and further relief to which Plaintiff may be justly entitled.

Respectfully Submitted,

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